

TECHNOLOGY TRANSFER IN PHARMACEUTICAL INDUSTRY: A COMPREHENSIVE REVIEW

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ABSTRACT

Technology transfer in the pharmaceutical industry is a critical process that facilitates the efficient transfer of knowledge, skills, and processes from research and development to manufacturing and production. This comprehensive review delves into various aspects of technology transfer, including its significance, challenges, best practices, regulatory considerations, and its impact on drug development and accessibility. By exploring the importance of collaboration and partnerships in the technology transfer process, this review aims to provide insights into optimizing technology transfer for faster market entry and improved patient access to life-saving medicines. The integration of best practices, adherence to regulatory guidelines, and successful cross-functional collaboration are essential for achieving seamless technology transfer and enhancing pharmaceutical manufacturing efficiency. This review aims to highlight the significance of technology transfer in promoting drug accessibility and patient care while laying the groundwork for future advancements in the pharmaceutical industry.

Keywords – *Technology transfer, Pharmaceuticals, Dosage forms, Regulatory guidelines, US FDA.*

1. INTRODUCTION

In the pharmaceutical industry technology transfer refers to the processes that are needed for successful progress from drug discovery to product development, to clinical trials to full-scale commercialization or it is the process by which a developer of technology makes its technology available to commercial partner that will exploit technology. In pharmaceutical industry preparation of dosage form needs scale up at several stages, such as small-scale laboratory development from 0.5-2kg batch can be scaled up to 5-10 kg and then to 20-100 kg on a pilot scale. Production scale can typically range from 200 kg to greater than 1000kg. Technology transfer involves manufacturing drug product with increasing batch sizes on larger equipment or using continuous processing on pilot scale equipment. Generally, scale up involves the transfer of technology and the transfer of knowledge that has been accumulated during the small-scale development of product and processes. It is important to realize that good communication is critical for formulation and process transfer to be successful. It is essential for a researcher or developer of technology to make available this technology to another person's to exploit for the progress of development of technology and for exploitation of a technology in different fields of applications and to make its use with another organization that may have better manufacturing capability, marketing capability and commercial capability. In the pharmaceutical industry,

technology transfer by collaborating with other departments and other organizations to commercialize a pharmaceutical product is a common process.

A technology transfer is a complex process that involves different types of expertise. Some of those are:

- a) Knowledge transfer
- b) Experience sharing
- c) Communications, and
- d) Inter and intra-company cooperation on a large scale.

The drug quality is designed based on basic data concerning efficacy and safety obtained from various studies in preclinical phases and data concerning efficacy, safety and stability of drug products obtained from clinical studies. The quality of design will be almost completed in Phase II clinical study. Various standards for manufacturing and tests will be established in process of reviewing factory production and Phase III study to realize the quality of design, and the quality of design will be verified in various validation studies, and will be upgraded to be the quality of product, and the actual production will be started. The technology transfer consists of actions taken in these flows of development to realize the quality as designed during the manufacture. Even if the production starts, the technology transfer will take place in processes such as changes in manufacturing places.

Technology transfer is a crucial process in the pharmaceutical industry that involves the efficient and seamless transfer of knowledge, skills, and processes from research and development to manufacturing and production [1]. This review aims to explore the various aspects of technology transfer in the pharmaceutical sector, including its challenges, best practices, regulatory considerations, and its impact on drug development and accessibility [2].

1.1 Importance of Technology Transfer in Pharmaceutical Industry: Technology transfer plays a pivotal role in bridging the gap between drug discovery and commercialization [3]. It enables pharmaceutical companies to scale up production, improve efficiency, ensure quality, and enhance regulatory compliance [4]. The successful transfer of technology facilitates the rapid availability of life-saving medicines to patients worldwide [5].

1.2 Technology Transfer Process and Best Practices: The technology transfer process involves several stages, including pre-transfer planning, development of the transfer plan, process validation, and post-transfer monitoring [6]. Effective project management, clear communication, and well-documented procedures are essential best practices in technology transfer to ensure its success [7].

1.3 Challenges in Technology Transfer: Various challenges can hinder the seamless transfer of technology in the pharmaceutical industry [8]. These challenges may include intellectual property protection, regulatory compliance, equipment and facility validation, cross-functional collaboration, and managing cultural differences in multi-site transfers [9]. The Obstacles confronted in technology transfer are as summarized below:

- a) Lack of a persistent framework for the understanding of the technology concept.
- b) Absence of procedures for receiving technology transfer in developing countries.
- c) In the progress of technology transfer, there is a lack of bilateral benefits.
- d) Unavailability of the persistent framework for analysis and evaluation of technology.
- e) Ergonomic aspects are failed to integrate into technology transfer.
- f) Lack of scrutiny to environmental and assessment of technological consequences.
- g) The feasibility study of technology transfer is limiting money evaluation.

- h) Misjudgment of the concept of technology usefulness.
- i) In the technology transfer process presence of ethical issues [6, 7].

1.4 Regulatory Considerations: Regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have specific guidelines and requirements for technology transfer to ensure product quality, safety, and efficacy [10]. Compliance with Good Manufacturing Practices (GMP) and adherence to Current Good Manufacturing Practices (cGMP) are critical aspects of successful technology transfer [3]. Technology transfer comprises of knowledge transfer, science, and risk-based principles inclusive of ICH Q8, Q9, Q10, Q11, and proficient processes to satisfy evolving commercial needs. The role of various ICH guidelines is providing in fig. 1.

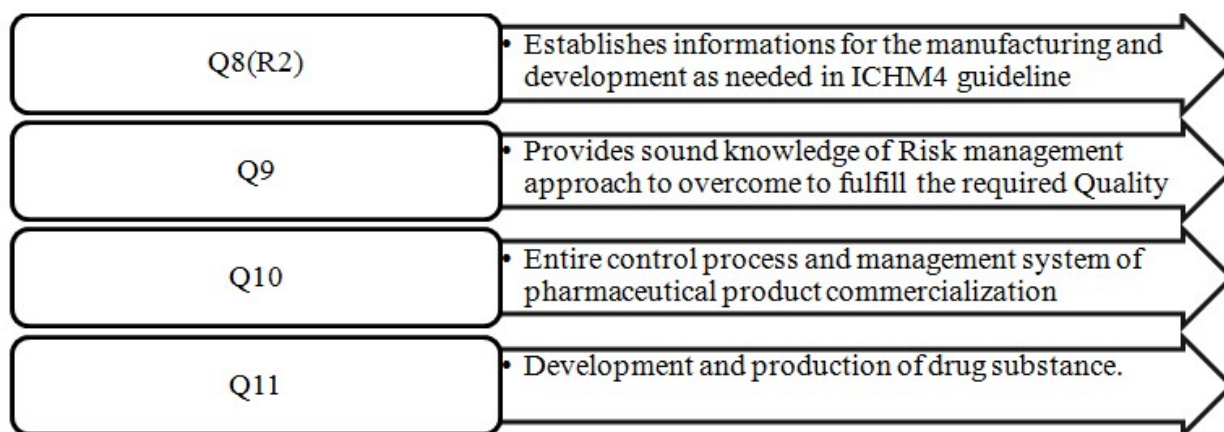


Fig. 1: Role of ICH guidelines

According to ICH Q10 guidelines, “The intention of technology transfer operations is to transfer process, and product information among the development and manufacturing sites, and within production sites to attain product realization. This information is the basis for the manufacturing of the product, monitoring strategies, process validation, and ongoing persistent improvement.”

To guarantee a successful technology transfer, pharmaceutical companies ought to create a collaborative improvement team must have the required qualification, knowledge, and skills to affect the transfer, originate a written controlling method to concentrate attention on crucial points in the process and equipment, review the process for inputs/outputs that might affect the quality of the product.

1.5 Impact on Drug Development and Accessibility: Efficient technology transfer can significantly impact drug development timelines, leading to faster market entry and increased patient access to innovative therapies [5]. By facilitating cost-effective manufacturing processes, technology transfer also contributes to reducing drug prices, making medications more affordable and accessible to patients [4].

1.6 Collaboration and Partnerships in Technology Transfer: Collaboration between pharmaceutical companies, contract manufacturing organizations (CMOs), and academic institutions plays a vital role in technology transfer [10]. These collaborations foster knowledge exchange, leverage expertise, and optimize resources for successful technology transfer [2].

2. STEPS INVOLVED IN TECHNOLOGY TRANSFER

2.1 Pre-Transfer Planning:

The technology transfer team consists of experts from research and development, process engineering, quality assurance, and regulatory affairs. The team's primary objective is to develop a comprehensive technology transfer plan, identifying critical process parameters, raw materials, and equipment requirements.

2.2 Process Development and Validation:

The technology transfer team conducts extensive process development studies to optimize the manufacturing process for large-scale production. They establish a robust process control strategy and also performs validation studies to ensure the process's consistency and reproducibility.

2.3 Facility Assessment and Upgradation:

The receiving manufacturing site underwent a thorough assessment to identify any gaps in equipment, infrastructure, and personnel capabilities. Upgrades are made to align the facility with the required standards for GMP compliance and to accommodate the unique requirements of the production.

2.4 Analytical Method Transfer:

The analytical team works in collaboration with the receiving site to transfer analytical methods for product testing and quality control. Method validation is performed to ensure accurate and reliable results.

2.5 Training and Skill Development:

To ensure smooth technology transfer, the receiving site's staff receives comprehensive training on the new manufacturing process, quality control, and adherence to GMP standards. Key personnel from the research facility are sometimes temporarily stationed at the receiving site to provide hands-on support and knowledge transfer.

2.6 Technology Transfer Execution:

With all preparations in place, the technology transfer process is initiated. The receiving site manufactures the batches under the supervision of both the research facility and receiving site experts. Regular meetings and communication channels were established to address any challenges and ensure a smooth transfer.

2.7 Process Performance Qualification (PPQ):

The receiving site conducted process performance qualification to demonstrate that the manufacturing process, when performed at full-scale, consistently produces products meeting quality standards. This step is crucial to gaining regulatory approval for commercial production.

2.8 Regulatory Submission and Approval:

The technology transfer team compiles all necessary documentation, including the technology transfer plan, validation reports, and quality control data, for regulatory submission. Regulatory authorities reviewed the submission, and upon successful inspection, granted approval for commercial manufacturing.

2.9 Post-Transfer Monitoring and Continuous Improvement:

Following the successful technology transfer and product launch, company implements a robust post-transfer monitoring program. This program included regular quality audits, periodic process reviews, and continuous improvement initiatives to optimize industrial production and maintain product quality.

3. REASONS FOR TECHNOLOGY TRANSFER

3.1 Lack of manufacturing capacity: The developer of technology may only have manufacturing equipment which is suitable for small scale operation, and must collaborate with another organization to do large scale manufacturing.

3.2 Lack of resources to launch product commercially: The original inventor of technology may only have the resources to conduct early-stage research such as animal studies and toxicology study, but doesn't have the resources to take technology through its clinical and regulatory phases.

3.3 Lack of marketing and distribution capability: The developer of technology may have fully developed the technology and even have obtained regulatory approvals and product registrations, but it may not have the marketing and distribution channels.

3.4 Exploitation in a different field of application: Each partner may have only half of the solution i.e. the developer of the technology might be capable of exploiting the technology itself in the field of diagnostic applications and may grant exploitation right to commercial partner for the exploitation of therapeutics application [11,12]

4. EFFECTIVE FACTORS IN TECHNOLOGY TRANSFER

Eight factors are critical in terms of creating favorable conditions for pharmaceutical technical transfers [13]:

- a) A viable and accessible local market;
- b) Political stability, good economic governance;
- c) Clear development priorities;
- d) Effective regulation;
- e) Availability of skilled workers;
- f) Adequate capital markets;
- g) Strong intellectual property rights (IPR) and effective enforcement;
- h) Quality of the relationship between industry and government, and the extent they are able to work together effectively for long periods of time.

4. TRANSFER PROTOCOL

The technology transfer protocol must list the intentional consecutive steps of the transfer. The transfer protocol should encompass:

- a) Objectives
- b) Scope
- c) Key personnel and their duties.
- d) A parallel assessment of materials, processes, and equipment.
- e) The technology transfer steps with documented proof that every single crucial step had been sufficiently accomplished earlier than the subsequent commences.
- f) Identity of important control measures.
- g) For analytical methods design and acceptance criteria
- h) Details on the pilot batches, qualification batches, and process validation.
- i) Change control procedure for any process discrepancies confronted.
- j) Evaluation of the end-product

- k) Provisions for retaining samples of active ingredients, intermediates, and finished drug products, and details on reference samples where appropriate.
- l) Conclusion includes signed-off approval by the project manager [14].

5. CONCLUSION

Technology transfer is an indispensable process in the pharmaceutical industry, streamlining drug development, manufacturing, and accessibility to patients. Addressing challenges and adopting best practices, while adhering to regulatory guidelines, is paramount for successful technology transfer. Through collaboration and partnerships, the pharmaceutical industry can continue to enhance technology transfer processes, leading to improved drug availability and patient care.

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